PARTICIPANT INFORMATION SHEET

FEASIBILITY STUDY OF AN ORAL DEVICE TO PROMOTE WEIGHT LOSS

Invitation to take part

You are being invited to take part in a research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Please discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

This study will try out a new treatment for overweight people. People can lose weight if they eat less, but most people can't stick to a diet for more than a week or two. This study tries out a new way of helping people to eat less and so stick to their diet. The idea is to use a very thin, lightweight device which fits over your back teeth. The little device fits over the upper and lower back teeth on both sides of the jaw. Each one contains tiny magnets, so that when you close your mouth, the magnets make it very difficult to chew (Figure 1). Instead of eating solid food, you will be given a liquid diet. This liquid diet is low in calories and so you should lose weight.

With the device in place you will be able to talk, drink, swallow, and breathe easily, but opening and closing your mouth, and so eating solid food, will be quite difficult. You will be able to open your mouth in an emergency and you will be shown how to do this.

A dentist will examine your teeth to see if they are suitable for you to wear the magnetic device. If you are suitable, the dentist will make the device to fit the shape of your teeth.

The main aim of the study is to see how you tolerate wearing the device and how comfortable it is, and how much weight you can lose in four weeks.

Figure 1: Device composed of metal bands and titanium magnets.

This study lasts four weeks. During that time, we will see if the bands are comfortable and if you find them acceptable as a treatment for losing weight. If you are happy with wearing the splints and you have started to lose weight, then you may be approached to carry on wearing the device for longer periods in future studies.

Why have I been chosen?

You have been chosen because losing weight would be helpful for your overall health. You should take part in this study if you have had difficulty in losing weight with diets in the past.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this Information Sheet to keep and be asked to sign a Consent form. If you decide to take part you are still free to withdraw from the study at any time and without giving your reason. If you decide to withdraw from the study at any time, or decide not to take part in the study, this will not affect you in any way.

What will my participation in the study involve?

Your teeth will be examined by a dentist to see if you are suitable to take part in this study. If your teeth are suitable, then the dentist will make the devices to fit your teeth. The devices will be applied so that you will find it difficult to chew and eat solid food. A dietitian will give you advice about a liquid diet, which you will be able to take and swallow easily. This liquid diet will be low in calories and so you should lose weight. The liquid diet will be provided to you for the duration of the study at no cost. The study will last for one month. During this time, you will be monitored by the research team at

24h, 3 days, 7 days, 14 days, 21 days and 28 days after device placement, and will be requested to fill in questionnaires about your experience with the device and the impact of weight on your quality of life. Some of these questions might be personal/sensitive.

At the end of four weeks, you will be weighed and your teeth inspected. You will be monitored for one year by the study multidisciplinary team to assess if the weight loss has continued or not, and if it has had any impact in the your eating habits and lifestyle. This monitoring involves phone calls and a visit to the study team after one year.

If you agree to take part in the study, you must agree to stick to the liquid diet while you are wearing the magnetic devices. If you try to eat and chew solid food, there is a chance that you could choke. If you do choke, you will be able to open your mouth and we will show you how to do this if there is an emergency. You must also agree to attend the clinic when requested for a checkup. Your transport costs will be covered for these visits.

All the participants in this study will try the device and your weight before and after taking part will be compared.

What do I have to do?

You must follow the diet advice that you are given and stick to the liquid diet. You must not take any solid food whilst you take part in the study. If you are on tablet medication, then this needs to be discussed with the doctor supervising the study, so that suitable medication is provided. You may need to crush your tablets or we may need to supply a liquid medication instead of tablets.

Explanation of the procedure that is being tested

This study will try out a magnetic device to make it difficult for people to chew, compared with being on their usual diet for weight reduction. In the past, people have had their jaws wired together to help them stop eating. Jaw wiring is a very effective way of losing weight, but it may be uncomfortable and cleaning your teeth can be difficult. The magnetic device tried in this study should be so comfortable so that you can't notice it is there, and you should be able to clean your teeth.

You also will be given a card stating that you are in a study of a new treatment for weight loss which gives the telephone details of the doctors supervising the trial.

Alternative treatment

Instead of using the magnetic device, you could have tablets to help you lose weight, or have an operation to staple and reduce your stomach, which means that you can only eat smaller meals.

What are the potential disadvantages and risks of taking part?

You may feel hungry on the liquid diet while you lose weight.

The device may feel uncomfortable and if it is, then you will need to have it adjusted by the dentist supervisor of the trial.

If you attempt to eat solid food there is a risk that you may choke. If you are sick, there is a chance that some vomit could go in your windpipe and cause choking. You will be shown how to open your mouth in an emergency, if necessary.

You may withdraw from participation in the study at any time and without any disadvantage to yourself.

How do I open my mouth in an emergency?

You may feel the need to open your mouth in an emergency, for example if you feel sick. You may be able to open your mouth if you try very hard with your jaw muscles. You can help by pulling your mouth open by holding your nose and your chin. You will also be given a metal tool to aid device opening, like a shoe horn, and be shown how to use it.

When the magnets are fitted, the dentist will make sure that you can open your mouth for emergencies.

EMERGENCY TELEPHONE NUMBER:

PROF. PAUL BRUNTON
Office - Faculty of Dentistry, University of Otago
9.00am – 5.00pm Monday - Friday
03 479 7039

Mobile: 021 2797041 24 hours

What are the possible benefits of taking part?

We hope that this treatment will help you and that you will lose some weight during the study.

What if new information becomes available?

While you take part in the study new information could become available about your treatment. You will be told if this happens and you will always have the choice of leaving the study at any time. If you leave the study, your normal care will continue. If you continue with the study, you will be asked to sign an updated consent form. If some new information becomes available, your research doctor may advise you to leave the study in your best interests. Any reasons for doing this and arrangements will be explained to you.

What happens when the research study stops?

At this stage, it is not intended for anybody to use the dental device for more than four weeks at a time. If you wish to continue for longer than four weeks, you could be entered in a further follow up study.

What happens if something goes wrong?

In the unlikely event that you are harmed by taking part in this research project, this could be covered under the terms of the accident compensation legislation with its limitations. While a claim may be lodged, it is always up to ACC to accept or decline your claim. If you have any questions about ACC, please feel free to ask the researcher for more information before you agree to take part in this study.

If you have any queries or concerns about your rights as a participant in this study, you may wish to contact the local Health and Disability Services Consumer Advocate:

Telephone: (03) 479 0265 or freephone 0800 377 766 or
Free fax: 0800 2787 7678 (0800 2 SUPPORT) or
Email: advocacy@hdc.org.nz

If there is a specific Maori issue or concern, please contact Prof. John Broughton, Assoc. Dean Maori.
Telephone: (03) 479 7639
Email: john.broughton@otago.ac.nz

Will taking part in the study be kept confidential?

If you consent to take part in this research study, your medical records will be inspected by the doctors and dentists conducting the study. If you take part, then this is confidential and no one else will know apart from you, the study doctors and dentists, and your GP will be informed. The fact that you are taking part in the study will be in the hospital notes and any other hospital doctor that needs to know this will be able to see this in your notes. The normal rules of Health Service confidentiality apply to this study.

When the project is completed, all personal identifying information will be removed from the paper records and electronic files which represent the data from the project. Paper records will be kept in locked cabinets. Electronic data will be stored on a password secured computer stored at the Faculty of Dentistry. The computers will be contained within locked rooms, in alarm activated area of the respective buildings. Data collected during the duration of this study will be stored for at least 10 years.

What will happen to the results of the research study?

If the research study shows a positive result, then the researchers will hope to publish the results in an appropriate journal within 12 months of the end of the study. All patients who take part in the study will be told the eventual results. Any publication will be confidential and the details of individual patients will not be made available to anyone outside the study. You cannot be identified personally from any publication about the study.

Who is organising and funding the research?

This study is organised by Prof. Paul Brunton, Dean of the Faculty of Dentistry, Prof. Jim Mann and Dr. Patrick Manning, the Edgar Diabetes and Obesity Research Center. The work on this study has been financed by the Faculty of Dentistry and other grants. None of the doctors or dentists conducting this research will be paid for carrying out the research. You will not be paid for taking part in the study and there are no expenses to be paid to you for travelling costs for you to attend for your appointments.

Contact for further information

If you require any further information then please feel free to discuss this with Prof. Paul Brunton at the Faculty of Dentistry, University of Otago, telephone 03 479 7039.

You will be given a 24 hour helpline number in case of problems.

CONSENT FORM

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Please tick to indicate consent to the following:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
I consent to the research staff collecting and processing my information, including information about my health.
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
I understand the compensation provisions in case of injury during the study.
I know who to contact if I have any questions about the study in

general.

I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study.

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: